



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0126]

Compliance Policy Guide Regarding Food Facility Registration--Human and Animal Food;
Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of Compliance Policy Guide Sec. 100.250 Food Facility Registration--Human and Animal Food (the CPG). The CPG provides guidance for our staff on enforcement of food facility registration requirements.

DATES: Submit either electronic or written comments on FDA's CPGs at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the

SUPPLEMENTARY INFORMATION section for electronic access to the CPG.

Submit electronic comments on the CPG to <http://www.regulations.gov>. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mischelle B. Ledet, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College

Park, MD 20740, 240-205-1165; or Kim R. Young, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9207.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of Compliance Policy Guide Sec. 100.250 Food Facility Registration--Human and Animal Food. The CPG is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The CPG provides guidance for FDA staff regarding enforcement of the food facility registration provisions of section 415 of the FD&C Act (21 U.S.C. 350d), including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration. The CPG also contains information that may be useful for the regulated industry and to the public.

In the Federal Register of April 4, 2013 (78 FR 20326), we made available draft CPG Sec. 100.250 Food Facility Registration--Human and Animal Food and gave interested parties an opportunity to submit comments by May 6, 2013, for us to consider before beginning work on the final version of the CPG. We received two comments on the draft CPG. We are issuing the CPG with no substantive changes, but made editorial changes for clarity.

The CPG announced in this notice finalizes the draft CPG dated April 2013. The CPG replaces CPG Sec. 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

II. Comments

Interested persons may submit either electronic comments regarding the CPG to <http://www.regulations.gov> or written comments regarding the CPG to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the CPG at either <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the CPG.

Dated: May 27, 2014.

Melinda K. Plaisier,

Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.